SC:JDL/AK/EA
F.#2015R00205

CR 15 62

CHEN, J.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA

- against -

MED PREP CONSULTING, INC.,
GERALD TIGHE and
STEPHEN KALINOSKI,

Defendants.

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INDICTMENT

Cr. No. _____
(T. 18, U.S.C., §§ 371, 981(a)(1)(C), 1343, 1349, 2 and 3551 et seq.; T. 21, U.S.C., §§ 331(a), 331(p), 333(a)(2), 334(a)(1), 351(a)(1), 351(a)(2)(A), 352(a), 352(j) and 853(p); T. 28, U.S.C., § 2461(c))

THE GRAND JURY CHARGES:

INTRODUCTION

Unless stated otherwise, at all times relevant to this Indictment:

I. Defendants and Relevant Entities

1. Defendant MED PREP CONSULTING, INC. ("MED PREP") was a medical drug repackager located and incorporated in New Jersey in 1994. MED PREP manufactured, repackaged, processed, packed, labeled, held, compounded and distributed articles of "drug" within the meaning of 21 U.S.C. § 321(g)(1). MED PREP's drug products included pain management medications, anesthesia and operating room drugs, and oncology and dialysis drugs. MED PREP operated in various locations in New Jersey before closing its operations in 2013.

2. Defendant GERALD TIGHE was defendant MED PREP's founder, sole owner and president. He was responsible for and oversaw all aspects of MED PREP's

business, including, but not limited to, manufacturing and quality operations. As president of MED PREP, TIGHE was the highest ranking corporate official with the greatest responsibility for the operations of MED PREP.

3. Defendant STEPHEN KALINOSKI was defendant MED PREP's director of pharmacy and its registered pharmacist in charge. He worked at MED PREP from approximately 2003 to its closing in the summer of 2013. KALINOSKI was in charge of MED PREP's repackaging and compounding operations and all other drug-processing activity.

4. The United States Food and Drug Administration (the "FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("the FDCA" or "the Act"), by ensuring that drugs intended for use in humans were safe and effective for their intended uses, and by ensuring that the labeling of such drugs bore true and accurate information. Pursuant to that responsibility, the FDA published and administered regulations relating to the approval, manufacture, labeling and distribution of drugs.

II. Requirements of the Act and Other Applicable Law

A. Definitions

5. A "drug" was an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings and an article (other than food) intended to affect the structure or any function of the body of a human being. 21 U.S.C. § 321(g)(1)(B) and (C).

6. The term "label" was defined as a display of written, printed or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling"

was broader and included all labels and other written, printed or graphic matter upon any article, including drugs, or any of its containers or wrappers, or on any written, printed or graphic matter accompanying such article. 21 U.S.C. § 321(m).

B. Adulteration

7. Drugs were considered adulterated if they consisted in whole or in part of any filthy, putrid or decomposed substance. 21 U.S.C. § 351(a)(1).

8. Drugs were also considered adulterated if they were prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health, whether or not the drugs were actually defective in some way. 21 U.S.C. § 351(a)(2)(A).

9. It was illegal for anyone to introduce, deliver for introduction or cause the introduction or delivery for introduction of adulterated drugs into interstate commerce. 21 U.S.C. § 331(a).

C. Misbranding and FDCA Labeling Requirements

10. Drugs were considered misbranded if their labeling was false or misleading in any particular. 21 U.S.C. § 352(a).

11. Drugs were also considered misbranded if they were dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling. 21 U.S.C. § 352(j).

12. It was illegal for anyone to introduce, deliver for introduction or cause the introduction or delivery for introduction of misbranded drugs into interstate commerce. 21 U.S.C. § 331(a).

E. The United States Pharmacopeia

13. The United States Pharmacopeial Convention was a scientific non-profit organization that published the United States Pharmacopeia ("USP"), which established professional standards for the identity, strength, quality and purity of drugs.

14. New Jersey Administrative Code 13:39-6.2(f)(9) required all pharmacists licensed in the State of New Jersey to comply with professional standards, federal statutes, rules and regulations governing the practice of pharmacy.

15. Chapter 797 of the USP ("USP 797") set forth professional standards for compounding drugs identified as sterile. USP 797's standards were meant to prevent harm to patients that could result from non-sterility, which was especially dangerous to patients when the drugs would be administered into their body cavities and vascular and central nervous systems. Provisions of USP 797 are summarized below.

16. USP 797 required scrupulous attention to cleaning and disinfecting the sterile compounding areas to minimize the potential for microbial contamination of sterile drugs.

17. USP 797 required that drugs must be compounded in an International Organization of Standardization ("ISO") Class 5 air quality environment or better. USP 797 also required that all high-efficiency particulate air ("HEPA") filters installed in a cleanroom be efficiency-tested and leak-tested before and after their installation.

18. USP 797 required surface and air sampling of sterile compounding areas. USP 797 identified airborne contaminants, microbial contamination from improperly cleaned and disinfected work surfaces and physical contact by personnel to be major sources

of contamination of sterile drugs. USP 797 provided that these potential contaminants should be given highest priority in a compounding facility.

19. USP 797 required a compounding facility to establish "action" levels for microbial contamination. If surface or air sampling revealed contamination above an "action" level, USP 797 required a re-evaluation of the compounding facility's practices and procedures. In addition, USP 797 required an investigation into the source of the contamination, the elimination of the source, re-cleaning and re-disinfecting of the area, and re-sampling.

20. USP 797 required compounding personnel to be adequately skilled, educated, instructed and trained to properly compound sterile drugs. USP 797 set forth requirements for the garbing and gowning of personnel involved in compounding, and for how those personnel should wash before entering the compounding area. USP 797 required that any personnel who were suffering from any skin-shedding condition were prohibited from preparing sterile drugs.

21. Since June 2008, USP 797 required gloved fingertip sampling of all compounding personnel, and further required routine application of sterile 70% isopropyl alcohol to gloved hands to prevent direct touch contamination of sterile drugs. If the personnel gloved fingertip sampling consistently revealed elevated levels of microbial growth, USP 797 required the compounding facility to consult with competent microbiology personnel.

22. USP 797 required that all equipment and supplies be wiped with a suitable disinfecting agent, such as sterile 70% isopropyl alcohol, and allowed to dry before use in the compounding process.

23. USP 797 provided that a drug product had to bear a "beyond use" or "use by" date, which was a date or time after which a compounded sterile preparation should not be stored or transported. USP 797 also provided that the use by date had to be determined from the date that the preparation was compounded. USP 797 provided that the use by dates set forth in that chapter could not be exceeded unless the compounder had performed adequate sterility testing pursuant to Chapter 71 of the USP.

24. In order to gain market share, defendant MED PREP repeatedly represented to healthcare providers that it complied with, and in some areas exceeded, the requirements set forth in USP 797. By virtue of the requirements set forth in USP 797, and MED PREP's assurances that it was in compliance with such requirements, patients and healthcare providers had an expectation that the drugs they received would be sterile and stable, contain the actual ingredients represented in the label and the correct amount of ingredients, so as to contain the expected potency and be safe and effective at all times prior to the use by date listed on those drugs.

III. Defendant MED PREP's Operations

A. Overview of the Business

25. Defendant MED PREP manufactured, repackaged, processed, packed, labeled and distributed drugs. Prior to approximately March 2002, MED PREP trained pharmacy technicians that the company then sent out to work on-site at hospitals. At the hospitals, the pharmacy technicians drew drugs from vials into syringes. After approximately March 2002, MED PREP changed its business model and performed all of its services at its own facility.

26. Defendant MED PREP's customers consisted primarily of hospitals, large oncology centers and multidisciplinary medical practices (collectively, "healthcare providers") in several states, including New York, Connecticut, Florida and New Jersey.

27. In some years, defendant MED PREP provided services for a total of more than 100 drugs across three product lines: syringes, intravenous ("IV") bags and pumps. All of this was done in a so-called cleanroom and ante-room space that was approximately 1,000 square feet. At times, approximately 18 employees with exposed skin and exposed street clothing worked in that space.

28. With respect to the drug products defendant MED PREP manufactured for healthcare providers, MED PREP first received the components of such drug products, including active ingredients and diluents if necessary, from the healthcare providers. Next, MED PREP produced the final products — and in the case of the vial-to-syringe program, transferred the products from the vials into the syringes — then froze or refrigerated the products as needed and then shipped or otherwise delivered the products to healthcare providers. Some of these healthcare providers were located in the Eastern District of New York.

29. Many of defendant MED PREP's drug products were ultimately intended to be injected into patients' vascular systems. Nonsterility, contamination, incorrect components and errors in strength of correct components in sterile drug products are especially dangerous when the drugs are administered into vascular systems.

30. Defendant MED PREP did not receive any prescriptions for identified individual patients for the drugs it manufactured, processed and repackaged.

B. The Vial-to-Syringe Program

31. Under defendant MED PREP's vial-to-syringe program, the company repackaged vials of expensive injectable drugs into syringes. The drugs available through MED PREP's vial-to-syringe program included Aranesp, Avastin, Epogen, Neupogen, Procrit, Rituxan, Xgeva and Zometa. These eight drugs were primarily used to treat cancer or to prevent or treat the side effects of cancer therapies.

32. Each vial of drug sent from a healthcare provider to defendant MED PREP contained "overfill," which was excess drug product included by the manufacturer to ensure that physicians would be able to draw into a syringe the precise amount of product to be administered to the patient. In other words, overfill was included so that even after any evaporation, spillage or other circumstances that could lead to lost drug product, the patient received the full dose needed. By collecting and using the overfill from the vials to fill the syringes, MED PREP was able to send back to healthcare providers a greater number of syringes than the number of vials it received from them. For this service, MED PREP charged what it called in some contracts a "repackaging fee." It was MED PREP's practice to extract the overfill from each vial in one of two ways explained below.

33. For certain drugs, defendant MED PREP drew up all of the drug product from multiple vials into an IV bag, thereby pooling drug product from multiple vials and sometimes mixing distinct lots. MED PREP would then dispense the pooled drug product into multiple syringes, filling each syringe with just enough drug product for a correct dose, assuming no evaporation, spillage or other circumstances that could lead to lost drug product.

34. For other drugs, defendant MED PREP would first extract overfill from several individual vials using the same syringe. Thus, this syringe would enter a number of vials to create one complete dose from overfill. MED PREP would then reenter the vials, this time with a new syringe for each vial, to extract the remaining full dose from each vial. These syringes were sent back to healthcare providers for administration to patients. Often, these vials of drug product were preservative-free and specified for single-use only.

35. Both processes — pooling and reentering vials — if not conducted with scrupulous attention to aseptic technique, significantly heightened the risk that sterility would be compromised and that the drug product would become contaminated.

36. By deliberately mixing overfill from distinct lots of vials from the original manufacturer of the active ingredients in its drugs, defendant MED PREP made it more difficult to track a contamination event back to a particular lot in the event the original ingredient as received by Med Prep was in some way compromised or contaminated.

IV. The Schemes to Violate the FDCA and to Defraud Healthcare Providers

37. In or about and between January 2007 and April 2013, defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI, together with others, conspired to introduce and introduced, or caused the introduction of, adulterated and misbranded drugs into interstate commerce, all with the intent to defraud and mislead the FDA and healthcare providers. In so doing, the defendants violated the law and created serious risks for patients who were being treated for cancer and other illnesses.

38. The adulterated drugs that defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI introduced or caused the introduction of into interstate

commerce were adulterated because they were prepared, packed and held under insanitary conditions and because the drugs consisted in whole or in part of a filthy, putrid and decomposed substance.

39. The misbranded drugs that defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI introduced or caused the introduction of into interstate commerce were misbranded because the drugs were dangerous to health when used as labeled and because the labeling on the drugs regarding use by dates and the strength of the ingredients was false and misleading.

40. In or about and between January 2007 and April 2013, defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI, together with others, executed a scheme to defraud healthcare providers. The defendants assured healthcare providers that they were receiving drug products from MED PREP that were produced in full compliance with the law, were compounded and packaged in compliance with USP 797 and would be safe for patients. The defendants also told healthcare providers that the beyond use dates that the defendants assigned to sterile drug products were supported by sterility testing that satisfied the requirements of USP 797. These representations were made in, among other places, quarterly Quality Trend Record Review Summary reports that were sent by e-mail to the healthcare providers. The defendants did not inform healthcare providers of failures to comply with USP 797 and basic sterility practices, and breaches of aseptic technique in MED PREP's cleanroom, that occurred repeatedly at MED PREP's facility. In sum, the defendants misrepresented the quality of their drug processing and repackaging operation in order to increase market share, and they engaged in substandard practices in order to save money and increase their profits. Relying on these misrepresentations and omissions, healthcare

providers paid MED PREP approximately $34,970,881 for its services between approximately 2007 and 2012.

A. The Defendants' History of Inspections by the FDA

41. Defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI had a long history of poor manufacturing practices.

42. Consumer Safety Officers ("CSOs") from the FDA inspected the various facilities out of which defendant MED PREP operated on multiple occasions between 2000 and 2009. MED PREP was initially inspected in January 2000. Numerous deficiencies were noted during this inspection. In conversation and in a written report, the FDA emphasized that, among other things, when MED PREP personnel entered a single-use, preservative-free vial of drug product for a second time as part of its vial-to-syringe program, there was no assurance of the sterility of the drug product after the initial entry; that there was insufficient data to support the beyond use dates that MED PREP assigned to drug products; and that MED PREP was not conducting sterility testing of its drug products.

43. Defendant MED PREP was again inspected in April 2001. The FDA again communicated its concerns in conversation and in a written report. These concerns again included that when MED PREP personnel entered a single-use, preservative-free vial of drug product for a second time as part of its vial-to-syringe program, there was no assurance of the sterility of the drug product after the initial entry, and that there was insufficient data to support the beyond use dates that MED PREP assigned to drug products. The FDA also expressed concern that MED PREP was conducting insufficient sterility testing because it was testing only one batch of drug product once a month.

44. The FDA again inspected defendant MED PREP in October 2002. At that time, the FDA observed that repackaging of single-use, preservative-free drug vials into syringes appeared to have ceased. When the FDA next inspected defendant MED PREP in 2004, it noted that MED PREP was once again repackaging single-use, preservative-free drug vials into syringes. In conversation and in a written report, the FDA emphasized that MED PREP's practice increased the risk of contamination of the drug product.

45. The FDA again inspected defendant MED PREP in December 2009. During this inspection, defendant GERALD TIGHE falsely represented to FDA CSOs that MED PREP was fully compliant with USP 797 and in many cases exceeded its standards. Defendant STEPHEN KALINOSKI told the FDA CSOs that MED PREP's HEPA filters were inspected every six months. KALINOSKI fraudulently omitted that three of the HEPA filters in MED PREP's cleanroom had failed their last two inspections by a third-party firm retained by MED PREP and had not been fixed.

46. On July 9, 2010, the FDA issued a Warning Letter to defendant MED PREP, again indicating the FDA's concern about MED PREP's practice of breaching the sterility of single-use, preservative-free vials of drug product by entering them a second time as part of its vial-to-syringe program.

B. Examples of Unsafe Practices at Defendant MED PREP

47. Despite numerous inspections and warnings, defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI continued to handle sterile drugs in conditions below acceptable industry standards. For instance, in or about May 2007, defendant STEPHEN KALINOSKI was advised that a MED PREP employee responsible for repacking and compounding in MED PREP's cleanroom had failed to treat an eczema skin

condition on his face for approximately five to six months while working in the cleanroom. Eczema is a term applied to a range of persistent inflammatory skin conditions characterized by recurring skin rashes and the flaking off of skin. KALINOSKI directed the employee to remove the employee's skin flakes and apply ointment over the employee's eyebrows before entering the cleanroom. Defendants KALINOSKI, GERALD TIGHE and MED PREP did not prevent the delivery to, or issue a recall from, healthcare providers of any of the drug products with which the employee had been in contact.

48. In addition, in January 2009, defendant MED PREP was informed that three of its HEPA filters had failed their inspections. These three HEPA filters, and eventually a fourth HEPA filter as well, failed inspections every six months for ten inspection periods, spanning five years, until MED PREP ceased operations.

49. In addition, a cart was regularly pushed from defendant MED PREP's unsterile warehouse into the purportedly sterile cleanroom without first being sterilized.

50. As a final example, instead of using sterile isopropyl alcohol to clean surfaces in the cleanroom in accordance with revised USP 797 standards that went into effect in June 2008, defendant MED PREP continued to use non-sterile isopropyl alcohol. Among other deficiencies, non-sterile isopropyl alcohol is inadequate to kill mold spores. Notably, sterile isopropyl alcohol costs several times more than non-sterile isopropyl alcohol.

C. Assigning of Unsupported Use By Dates on Drug Products

51. Although defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI received products with expiration dates assigned by the manufacturer, after the defendants removed products from their original containers, they illegally assigned new, unsupported use by dates to the products. For some drugs, such as Heparin, there had been

no study conducted to support the use by date that the defendants had affixed. For other drugs, such as magnesium sulfate, the defendants conducted a stability study but affixed use by dates that were much later than their own study purported to support. MED PREP failed to perform adequate sterility testing on either drug, or any of its drugs, to support its beyond use dating.

52. The vial-to-syringe program maintained by defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI also violated the instructions in the FDA-approved label for single-use, preservative-free vials. In a so-called "cleanroom" that failed to comply with basic industry standards, the defendants split, pooled and re-entered single-use, preservative-free vials of certain drugs in contravention of explicit instructions on the FDA-approved labels of the drugs.

53. For example, the FDA-approved manufacturers' labels for Procrit and Epogen made clear that the single-use vials did not contain preservative, and that once the seal was broken the drugs should have been used or discarded. The defendants did not follow these manufacturers' labels for Procrit and Epogen or similar labels for Aranesp, Avastin and Rituxan. In direct contravention of those instructions, the defendants opened the single-use vials, destroyed the documented sterility of the original vials, exposed the drugs to air and possible contaminants in an environment that did not meet standards for processing sterile drug products, and repackaged the drugs into syringes. In addition, the defendants then affixed new labels with 42-day use by dates which were wholly unsupported by appropriate sterility testing. Further, the FDA-approved labels for multi-use vials of Procrit and Epogen that did contain preservatives recommended that these drug products be discarded 21 days after a vial was breached. Yet, defendants MED PREP, GERALD TIGHE

and STEPHEN KALINOSKI affixed new labels with a 42-day use by date, a date that was twice as long as the date permitted by the original manufacturer's label and for which the defendants failed to conduct any sterility testing.

54. Defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI used these fraudulently-derived use by dates to induce healthcare providers to use MED PREP's services. TIGHE and KALINOSKI told healthcare providers that the healthcare providers could store the product longer than permitted by the instructions on the manufacturer's label, in some cases twice as long, and that the drug would continue to remain stable and safe for use in patients. Thus, the use of fraudulently extended use by dates gave MED PREP an advantage over competitors and caused healthcare providers to choose MED PREP's services.

D. Examples of Superpotent, Contaminated and "Cloudy" Drugs that the Defendants Sent to Healthcare Providers

i. Superpotent potassium phosphate

55. Potassium phosphate can be taken orally or intravenously to treat blood phosphate levels that are too low and blood calcium levels that are too high, and to prevent kidney stones. Potassium phosphate is also used to treat osteomalacia (typically called "rickets"), a condition often afflicting children that causes bones to soften due to a mineral imbalance, as well as gastroesophageal reflux disease, and can be used as a pre-surgical laxative.

56. On or about December 15, 2011, the director of pharmacy at a hospital in Brooklyn, New York ("Hospital #1"), whose identity is known to the Grand Jury, discovered that potassium phosphate sold to the hospital by defendant MED PREP had been

prepared at twice the concentration requested by the hospital. Drugs prepared with too high a concentration of the active ingredient are described as "superpotent." Superpotent drugs can have serious adverse effects on patients.

ii. Contaminated magnesium sulfate

57. Magnesium sulfate is used to treat certain conditions in pregnant women, cardiac patients and cancer patients, and is injected into the bloodstream or muscles of such patients.

58. On or about March 13, 2013, a hospital in New Haven, Connecticut ("Hospital #2"), whose identity is known to the Grand Jury, discovered that four IV bags of magnesium sulfate sold to the hospital by defendant MED PREP, and labeled as sterile, had visible floating particles and were potentially contaminated. Further investigation revealed that, in or about and between February 1, 2013 and March 1, 2013, defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI, had sent the hospital at least four distinct shipments of magnesium sulfate drug product that were contaminated.

59. Hospital #2 notified defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI of the floating particles in the magnesium sulfate on or about March 13, 2013. Hospital #2 cultured a sample of the magnesium sulfate that had been provided by MED PREP and determined that the floating particles were mold.

60. Subsequent analysis by a third-party laboratory retained by defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI also revealed that in each of the four shipments of magnesium sulfate, mold was present. One of the species of mold found in the contaminated magnesium sulfate was the same species of mold found in MED

PREP's warehouse, from where an unsterilized cart was regularly pushed into MED PREP's purportedly sterile cleanroom without first being sterilized.

61. Hospital #2 determined that at least 21 patients received magnesium sulfate from the contaminated lot shipped by defendant MED PREP. These patients were on the hematology and oncology ward and, after the contamination was discovered, were treated with anti-fungal antibiotics.

iii. "Cloudy" Avastin

62. Avastin is a drug used to treat colon cancer, lung cancer and kidney cancer.

63. On or about March 14, 2013, approximately one day after Hospital #2 discovered the floating particles in magnesium sulfate IV bags, defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI learned that MED PREP had provided a customer in Florida (the "Florida Clinic"), whose identity is known to the Grand Jury, with Avastin syringes in which the customer observed "particle matter and a cloudy consistency" and "chunks of particles that look like cottage cheese."

64. When FDA investigators and NJBOP inspectors arrived on site at defendant MED PREP's facility the next day, on or about March 15, 2013, and specifically asked both defendants GERALD TIGHE and STEPHEN KALINOSKI about all recent contamination incidents and customer complaints, neither TIGHE nor KALINOSKI mentioned the complaint a day earlier by the Florida Clinic.

iv. Contaminated dexamethasone

65. Dexamethasone is a type of anti-inflammatory drug administered to, among others, cancer patients to minimize or counteract certain side effects of chemotherapy and to assist in tumor shrinkage.

66. On or about April 4, 2013, a third-party laboratory retained by defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI tested an IV bag containing dexamethasone that had been shipped by MED PREP to Hospital #2, retrieved by MED PREP, and then sent to the third-party laboratory for testing. Sterility testing of the dexamethasone revealed that it, too, was contaminated with mold.

E. The Problems Found by the FDA and NJBOP in the March 2013 Inspection of Defendant MED PREP's Facility

i. FDA Inspection Report

67. On or about March 15, 2013, after learning about the contamination of defendant MED PREP's purportedly sterile drug products that were distributed to Hospital #2, the FDA began an inspection of MED PREP's facility, which was concluded on or about April 3, 2013 (the "March 2013 Inspection"). FDA investigators also collected samples of some of the defendants' drug products.

68. During the March 2013 inspection, FDA investigators documented insanitary conditions and numerous, significant failures of process. For example, FDA investigators discovered that defendants MED PREP, GERALD TIGHE and STEPHEN KALINOSKI had encountered numerous incidents of microbiological contamination in both tests of finished drug products and in "performance challenges," which were tests of the repackaging and compounding process that the defendants performed in order to evaluate

pharmacists' and pharmacy technicians' aseptic technique. FDA investigators also found that MED PREP shipped drug products to its healthcare providers that were mislabeled with incorrect drug strengths in some instances and were labeled as the wrong drugs altogether in other instances.

69. At the end of the March 2013 Inspection, on or about April 3, 2013, the FDA issued the defendants a Notice of Inspectional Observations detailing the investigators' observations. Among other things, the FDA observed that:

a. Defendant MED PREP failed to establish and follow appropriate written procedures, including the validation of all aseptic and sterilization processes, designed to prevent microbiological contamination of drug products purporting to be sterile;

b. MED PREP failed to establish a scientifically sound and appropriate sampling plan and testing procedures designed to assure that drug products conformed to appropriate standards of identity, strength, quality and purity;

c. MED PREP failed to conduct sterility testing for each batch of product that purported to be sterile and failed to establish or follow written testing procedures;

d. MED PREP failed to follow written procedures designed to assure that correct labels and packaging materials were used for drug products. This included a failure to follow procedures designed to prevent mix-ups and cross-contamination by physical or spatial separation from operations on other drug products;

e. MED PREP failed to conduct antimicrobial effectiveness testing to support drug product use by dates for sterile drug products containing preservatives;

f. MED PREP did not determine appropriate use by dates because it failed to test an adequate number of batches of each drug product;

g. MED PREP personnel engaged in the processing of drugs lacked appropriate sterile protective apparel; and

h. MED PREP failed to demonstrate the effectiveness of the cleaning agents used to conduct its operations.

ii. NJBOP Inspection Report

70. After the contamination incident with defendant MED PREP's shipments of magnesium sulfate and dexamethasone to Hospital #2, NJBOP conducted an investigation of MED PREP's compounding activities. On or about May 14, 2013, NJBOP issued its report of its investigation of MED PREP. The NJBOP report included the following deficiencies:

a. Contamination was confirmed in ten units from five separate batches involving two different drugs;

b. MED PREP failed to accurately document the personnel who participated in the compounding of the contaminated drugs;

c. Personnel responsible for quality control activities at MED PREP were also involved in actual compounding of the drug products;

d. Despite knowing that its HEPA filters were leaking, MED PREP failed to replace or repair them. MED PREP also failed to perform environmental testing in a dynamic cleanroom condition during operating hours;

e. MED PREP obtained several environmental testing results that indicated problematic conditions, yet failed to perform an investigation to determine the causes of those results to prevent future incidents;

f. MED PREP indicated a beyond use date of 45 days at room temperature on magnesium sulfate IV bags, though, pursuant to USP 797, a medium-risk drug product such as magnesium sulfate has a storage time of thirty hours at room temperature;

g. MED PREP's cleaning and disinfecting practices were deficient in several respects, which could lead to quality control issues. The deficiencies included the use of only non-sterile isopropyl alcohol to clean surfaces, failure to sterilize rolling carts before entering the cleanroom and failure to sterilize bags and components before entering the cleanroom;

h. MED PREP experienced several incidents and received several complaints from healthcare providers related to adverse events, mislabeled drugs and dispensing errors, which MED PREP failed to adequately investigate to prevent similar events in the future; and

i. MED PREP failed to implement a revised quality control protocol to assess and respond to complaints in a timely manner.

COUNT ONE
(Wire Fraud Conspiracy)

71. The allegations contained in paragraphs 1 through 70 are realleged and incorporated as though fully set forth in this paragraph.

72. In or about and between January 2007 and April 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, defendants MED PREP CONSULTING, INC., GERALD TIGHE and STEPHEN KALINOSKI, together with others, did knowingly and intentionally conspire to devise a scheme and artifice to defraud healthcare providers, and to obtain money and property from them by means of materially false and fraudulent pretenses, representations and promises, and for the purpose of executing such scheme and artifice, and attempting to do so, to transmit and cause to be transmitted, by means of wire communication in interstate and foreign commerce, writings, signs, signals, pictures and sounds.

(Title 18, United States Code, Sections 1349 and 3551 et seq.)

COUNTS TWO THROUGH SIXTEEN
(Wire Fraud)

73. The allegations contained in paragraphs 1 through 70 are realleged and incorporated as though fully set forth in this paragraph.

74. In or about and between January 2007 and April 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, defendants MED PREP CONSULTING, INC. ("MED PREP"), GERALD TIGHE and STEPHEN KALINOSKI, together with others, did knowingly and intentionally devise a scheme and artifice to defraud healthcare providers of MED PREP, and to obtain money and property from them by means of materially false and fraudulent pretenses, representations

and promises, and for the purpose of executing such scheme and artifice, did transmit and cause to be transmitted, by means of wire communication in interstate and foreign commerce, writings, signs, signals, pictures and sounds, as set forth below:

TWO	6/15/10	E-mail from defendant MED PREP in New Jersey to Hospital #1, in Brooklyn, New York, regarding use by date for epinephrine
THREE	6/23/10	E-mail from defendant MED PREP in New Jersey to a hospital on Long Island, New York ("Hospital #3"), whose identity is known to the Grand Jury, regarding beyond use dates for Heparin and hydromorphone
FOUR	7/29/10	E-mail from defendant KALINOSKI in New Jersey to Hospital #3, on Long Island, New York, regarding use by date for epinephrine
FIVE	8/10/10	E-mail from defendant MED PREP in New Jersey to Hospital #1, in Brooklyn, New York, and other healthcare providers, attaching Quality Trend Record Review Summary
SIX	10/25/10	E-mail from defendant MED PREP in New Jersey to Hospital #1, in Brooklyn, New York, and other healthcare providers, attaching Quality Trend Record Review Summary
SEVEN	2/23/11	E-mail from defendant MED PREP in New Jersey to Hospital #1, in Brooklyn, New York, and other healthcare providers, attaching Quality Trend Record Review Summary
EIGHT	8/18/11	E-mail from defendant MED PREP in New Jersey to Hospital #1, in Brooklyn, New York, and other healthcare providers, attaching Quality Trend Record Review Summary

NINE	9/15/11	E-mail from defendant MED PREP in New Jersey to a hospital on Long Island, New York (Hospital #4), whose identity is known to the Grand Jury, regarding use by dates for norepinephrine and phenylephrine
TEN	11/8/11	E-mail from defendant MED PREP in New Jersey to Hospital #1, in Brooklyn, New York, and other healthcare providers, attaching Quality Trend Record Review Summary
ELEVEN	2/27/12	E-mail from defendant MED PREP in New Jersey to a hospital on Long Island, New York ("Hospital #5"), whose identity is known to the Grand Jury, and other healthcare providers, attaching Quality Trend Record Review Summary
TWELVE	3/30/12	E-mail from defendant KALINOSKI in New Jersey to Hospital #5, on Long Island, New York, regarding use by date for Heparin
THIRTEEN	5/17/12	E-mail from defendant MED PREP in New Jersey to Hospital #5, on Long Island, New York, and other healthcare providers, attaching Quality Trend Record Review Summary
FOURTEEN	8/13/12	E-mail from defendant MED PREP in New Jersey to Hospital #5, on Long Island, New York, and other healthcare providers attaching Quality Trend Record Review Summary
FIFTEEN	11/21/12	E-mail from defendant MED PREP in New Jersey to a hematology and oncology practice in Queens, New York (the "Queens Clinic"), whose identity is known to the Grand Jury, and other healthcare providers, attaching Quality Trend Record Review Summary

SIXTEEN	1/31/13	E-mail from defendant MED PREP in New Jersey to Hospital #5, on Long Island, New York, and other healthcare providers attaching Quality Trend Record Review Summary

(Title 18, United States Code, Sections 1343, 2 and 3551 et seq.)

COUNT SEVENTEEN
(Conspiracy to Introduce Adulterated and Misbranded Drugs into Interstate Commerce)

75. The allegations contained in paragraphs 1 through 70 are hereby realleged and incorporated by reference as if fully set forth in this paragraph.

76. In or about and between January 2007 and April 2013, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, defendants MED PREP CONSULTING, INC. ("MED PREP"), GERALD TIGHE and STEPHEN KALINOSKI, together with others, did knowingly and intentionally conspire:

a. to introduce into interstate commerce, to deliver for introduction into interstate commerce and to cause the introduction and delivery for introduction into interstate commerce, with the intent to defraud and mislead, drugs that were adulterated in that they consisted in whole or in part of any filthy, putrid and decomposed substance, contrary to Title 21, United States Code, Sections 331(a) and 351(a)(1);

b. to introduce into interstate commerce, to deliver for introduction into interstate commerce and to cause the introduction and delivery for introduction into interstate commerce, with the intent to defraud and mislead, drugs that were adulterated in that they were prepared, packed and held under insanitary conditions whereby they may have been contaminated with filth, and whereby they may have been rendered injurious to health, contrary to Title 21, United States Code, Sections 331(a) and 351(a)(2)(A);

c. to introduce into interstate commerce, to deliver for introduction into interstate commerce, and to cause the introduction and delivery for introduction into interstate commerce, with the intent to defraud and mislead, drugs that were misbranded because they were dangerous to health when used in the dosage and manner, and with the

frequency and duration prescribed, recommended and suggested in the labeling thereof, contrary to Title 21, United States Code, Sections 331(a) and 352(j); and

d. to introduce into interstate commerce, to deliver for introduction into interstate commerce, and to cause the introduction and delivery for introduction into interstate commerce, with the intent to defraud and mislead, drugs that were misbranded because the labeling regarding use by dates was false and misleading and because the labeling misstated the potency of the ingredients, contrary to Title 21, United States Code, Sections 331(a) and 352(a).

77. In furtherance of the conspiracy and to effect its objectives, within the Eastern District of New York and elsewhere, defendants MED PREP CONSULTING, INC., GERALD TIGHE and STEPHEN KALINOSKI, together with others, committed and caused to be committed, among others, the following overt acts:

a. On or about August 10, 2010, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

b. On or about October 25, 2010, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

c. On or about February 23, 2011, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

d. On or about August 18, 2011, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

e. On or about September 20, 2011, KALINOSKI sent an email to an employee of a hospital in Bridgeport, Connecticut ("Hospital #6"), whose identity is known to the Grand Jury, stating that magnesium sulfate had a stability of 45 days at room temperature.

f. On or about November 8, 2011, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

g. On or about February 27, 2012, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

h. On or about May 17, 2012, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

i. On or about August 13, 2012, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

j. On or about November 21, 2012, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

k. On or about January 31, 2013, MED PREP's director of operations sent an e-mail to healthcare providers, attaching a Quality Trend Record Review Summary.

l. On or about January 31, 2013, KALINOSKI helped prepare a batch of magnesium sulfate for Hospital #2 that bore a use by date of 45 days.

(Title 18, United States Code, Sections 371 and 3551 et seq.)

COUNTS EIGHTEEN THROUGH TWENTY-TWO
(Introduction into Interstate Commerce of Drugs Adulterated Because Contaminated by Filth)

78. The allegations contained in paragraphs 1 through 70 are hereby realleged and incorporated by reference as if fully set forth in this paragraph.

79. On or about and between February 1, 2013 and March 4, 2013, both dates being approximate and inclusive, within the District of Connecticut and the District of New Jersey, defendants MED PREP CONSULTING, INC. ("MED PREP"), GERALD TIGHE and STEPHEN KALINOSKI did, with intent to defraud and mislead, introduce into interstate commerce, deliver for introduction into interstate commerce and cause the introduction and delivery for introduction into interstate commerce of drugs that were adulterated in that they consisted in whole or in part of any filthy, putrid and decomposed substance, as set forth below:

EIGHTEEN	2/1/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
NINETEEN	2/18/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
TWENTY	2/22/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
TWENTY-ONE	3/1/13	Dexamethasone sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
TWENTY-TWO	3/4/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut

(Title 21, United States Code, Sections 331(a), 333(a)(2) and 351(a)(1); Title 18, United States Code, Sections 2 and 3551 et seq.)

COUNTS TWENTY-THREE THROUGH TWENTY-SEVEN
(Introduction into Interstate Commerce of Drugs Adulterated Because of Insanitary Conditions)

80. The allegations contained in paragraphs 1 through 70 are hereby realleged and incorporated by reference as if fully set forth in this paragraph.

81. In or about and between June 2010 and November 2012, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, defendants MED PREP CONSULTING, INC. ("MED PREP"), GERALD TIGHE and STEPHEN KALINOSKI, did, with intent to defraud and mislead, introduce into interstate commerce, deliver for introduction into interstate commerce and cause the introduction and

delivery for introduction into interstate commerce of drugs that were adulterated in that they were prepared, packed and held under insanitary conditions whereby they may have been contaminated with filth, and whereby they may have been rendered injurious to health, as set forth below:

TWENTY-THREE	6/10/10	37 syringes of Avastin sent from defendant MED PREP in Tinton Falls, New Jersey, to the Queens Clinic, in Queens, New York
TWENTY-FOUR	6/18/10	120 syringes of Rituxan sent from defendant MED PREP in Tinton Falls, New Jersey, to the Queens Clinic, in Queens, New York
TWENTY-FIVE	7/2/10	107 syringes of Aranesp sent from defendant MED PREP in Tinton Falls, New Jersey, to the Queens Clinic, in Queens, New York
TWENTY-SIX	12/13/11	100 IV bags of potassium phosphate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #1, in Brooklyn, New York
TWENTY-SEVEN	11/27/12	120 IV bags of oxytocin and 40 IV bags of potassium chloride sent from defendant MED PREP in Tinton Falls, New Jersey, to a hospital in Queens, New York ("Hospital #7"), whose identity is known to the Grand Jury

(Title 21, United States Code, Sections 331(a), 333(a)(2) and 351(a)(2)(A); Title 18, United States Code, Sections 2 and 3551 et seq.)

COUNTS TWENTY-EIGHT THROUGH THIRTY-TWO
(Introduction into Interstate Commerce of Drugs Misbranded Because Dangerous to Health When Used as Labeled)

82. The allegations contained in paragraphs 1 through 70 are hereby realleged and incorporated by reference as if fully set forth in this paragraph.

83. On or about and between February 1, 2013 and March 4, 2013, both dates being approximate and inclusive, within the District of Connecticut and the District of New Jersey, defendants MED PREP CONSULTING, INC. ("MED PREP"), GERALD TIGHE and STEPHEN KALINOSKI, did, with intent to defraud and mislead, introduce into interstate commerce, deliver for introduction into interstate commerce and cause the introduction and delivery for introduction into interstate commerce of drugs that were misbranded because they were dangerous to health when used in the dosage and manner, and with the frequency and duration prescribed, recommended and suggested in the labeling thereof, as set forth below:

TWENTY-EIGHT	2/1/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
TWENTY-NINE	2/18/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
THIRTY	2/22/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
THIRTY-ONE	3/1/13	Dexamethasone sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut
THIRTY-TWO	3/4/13	Magnesium sulfate sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #2 in New Haven, Connecticut

(Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(j); Title 18, United States Code, Sections 2 and 3551 et seq.)

COUNTS THIRTY-THREE THROUGH THIRTY-SEVEN
(Introduction into Interstate Commerce of Drugs
Misbranded Because of False and Misleading Labeling)

84. The allegations contained in paragraphs 1 through 70 are hereby realleged and incorporated by reference as if fully set forth in this paragraph.

85. In or about and between June 2010 and November 2012, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, defendants MED PREP CONSULTING, INC. ("MED PREP"), GERALD TIGHE and STEPHEN KALINOSKI, did with intent to defraud and mislead, introduce into interstate commerce, deliver for introduction into interstate commerce and cause the introduction and delivery for introduction into interstate commerce of drugs that were misbranded because the labeling was false and misleading, as set forth below:

THIRTY-THREE	6/10/10	37 syringes of Avastin with use by date of 42 days sent from defendant MED PREP in Tinton Falls, New Jersey, to the Queens Clinic, in Queens, New York
THIRTY-FOUR	6/18/10	120 syringes of Rituxan with use by date of 42 days sent from defendant MED PREP in Tinton Falls, New Jersey, to the Queens Clinic, in Queens, New York
THIRTY-FIVE	7/2/10	107 syringes of Aranesp with use by date of 42 days sent from defendant MED PREP in Tinton Falls, New Jersey, to the Queens Clinic, in Queens, New York
THIRTY-SIX	12/13/11	100 IV bags of potassium phosphate, twice as potent as labeled, sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #1, in Brooklyn, New York
THIRTY-SEVEN	11/27/12	120 IV bags of oxytocin and 40 IV bags of potassium chloride with use by date of 45 days sent from defendant MED PREP in Tinton Falls, New Jersey, to Hospital #7, in Queens, New York

(Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(a); Title 18, United States Code, Sections 2 and 3551 et seq.)

CRIMINAL FORFEITURE ALLEGATION
AS TO COUNTS ONE THROUGH SIXTEEN

86. The United States hereby gives notice to the defendants that, upon their conviction of any of the offenses charged in Counts One through Sixteen, the government will seek forfeiture in accordance with Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), which require any person convicted of such offenses to forfeit any property constituting or derived from proceeds obtained as a result of such offenses, including, but not limited to, the real property and premises located at 26 South Arlene Drive, West Long Branch, New Jersey.

87. If any of the above-described forfeitable property, as a result of any act or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p) to seek forfeiture of any other property of the defendants up to the value of the forfeitable property described in this forfeiture allegation.

(Title 18, United States Code, Section 981(a)(1)(C); Title 21, United States Code, Section 853(p); Title 28, United States Code, Section 2461(c))

CRIMINAL FORFEITURE ALLEGATION
AS TO COUNTS SEVENTEEN THROUGH THIRTY-SEVEN

88. The United States hereby gives notice to the defendants that, upon their conviction of any of the offenses charged in Counts Seven through Thirty-Seven, the government will seek forfeiture in accordance with Title 21, United States Code, Section 334(a)(1) and Title 28, United States Code, Section 2461(c), which permit the forfeiture to the United States of any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce.

89. If any of the above-described forfeitable property, as a result of any act or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of such defendants up to the value of the forfeitable property described in this forfeiture allegation.

(Title 21, United States Code, Sections 334(a)(1) and 853(p); Title 28, United States Code, Section 2461(c))

A TRUE BILL

FOREPERSON

LORETTA E. LYNCH
UNITED STATES ATTORNEY
EASTERN DISTRICT OF NEW YORK

BY: _____
ACTING UNITED STATES ATTORNEY
PURSUANT TO 28 C.F.R. 0.136

F. #2015R00205
FORM DBD-34
JUN. 85

No.

UNITED STATES DISTRICT COURT

EASTERN *District of* NEW YORK

CRIMINAL DIVISION

THE UNITED STATES OF AMERICA

vs.

MED PREP CONSULTING, INC., GERALD TIGHE and STEPHEN KALINOSKI,

Defendants.

INDICTMENT

(T. 18, U.S.C., §§ 371, 981(a)(1)(C), 1343, 1349, 2 and 3551 et seq.; T. 21, U.S.C., §§ 331(a), 331(p), 333(a)(2), 334(a)(1), 351(a)(1), 351(a)(2)(A), 352(a), 352(j) and 853(p); T. 28, U.S.C., § 2461(c))

A true bill.

_____ *Foreperson*

Filed in open court this _____ *day, of* _____ *A.D. 20* __

_____ *Clerk*

Bail, $ _____

Justin D. Lerer, Assistant U.S. Attorney (718) 254-6024